K130469

5.0 510(k) SUMMARY

APR 0 5 2013

SUBMITTED BY:

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NAME OF DEVICE:

Trade Name: LIAISON® TSH
LIAISON® Control Thyroid 1
LIAISON® Control Thyroid 2
LIAISON® Control Thyroid 3

Common Names/Descriptions: Thyroid stimulating hormone

Classification Names: Thyroid stimulating hormone test system: Class II
21 CFR 862.1690; Clinical Chemistry (75)
Quality Control Material: Class I, reserved
21 CFR 862.1660; Clinical Chemistry (75)

Product Code: JLW, JJX

PREDICATE DEVICE:

Roche Elecsys® TSH Assay
Reference K961491 (Assay)
Elecsys® PreciControl Universal
Reference K090541 (Controls)

DEVICE DESCRIPTION:

INTENDED USE:
The DiaSorin LIAISON® TSH assay is an *in vitro* chemiluminescent immunoassay for the quantitative determination of thyroid stimulating hormone (TSH), also known as thyrotropin and thyrotropic hormone, in human serum. The test has to be performed on the LIAISON® XL Analyzer. Measurements of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.

The DiaSorin LIAISON® Control Thyroid 1, LIAISON® Control Thyroid 2 and LIAISON® Control Thyroid 3 are intended for use as assayed quality control samples to monitor the accuracy and precision of the DiaSorin LIAISON® TSH assay.

KIT DESCRIPTION:

The method for the quantitative determination of TSH is a sandwich chemiluminescence immunoassay. A specific mouse monoclonal antibody is coated on the magnetic particles (solid phase); another monoclonal antibody is linked to an isoluminol derivative (isoluminol-antibody conjugate). All assay steps and incubations are performed by the LIAISON® XL Analyzer.

Results are determined by a 2 point calibration conversion of the master curve to a working curve. The light signal, and hence the amount of isoluminol-antibody conjugate, is measured by a photomultiplier as relative light units (RLU) and is inversely related to TSH concentration present in calibrators, patient samples or controls.

COMPARISON TO PREDICATE DEVICE:

The DiaSorin LIAISON® TSH assay is substantially equivalent in principle and performance to the Roche Elecsys® TSH Test (K961491) which was FDA cleared July 22, 1996. The DiaSorin LIAISON® Control Thyroid 1, LIAISON® Control 2 and LIAISON® Control 3 are substantially equivalent in principle to the Roche Elecsys® PreciControl Universal (K090541).

Table 1: Table of Assay Similarities and Differences

Characteristic	New Device LIAISON® TSH	Predicate Device Roche Elecsys® TSH (K961491)
Intended Use	The DiaSorin LIAISON® TSH assay is a chemiluminescent immunoassay (CLIA) intended for the quantitative determination of thyroid stimulating hormone (TSH), also known thyrotropin and thyrotropic hormone in human serum. The test must be performed on the LIAISON® XL Analyzer.	Immunoassay for the *in vitro* quantitative determination of thyrotropin in human serum and plasma. The electrochemiluminescence Immunoassay "ECLIA" is intended for use on Elecsys and cobas e immunoassay analyzers.
Indications for Use	Measurements of TSH produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.	Same
Measured Analyte	Thyroid stimulating hormone also known as thyrotropin and thyrotropic hormone	Same
Assay Type	Chemiluminescent Immunoassay Sandwich principle	Electrochemiluminescent immunoassay Sandwich principle
Calibration	Two-point verification of stored master curve.	Same

Standarization	2nd IRP WHO Reference Standard 80/558	Same
Reagent Integral Storage	On-board or in refrigerator@ 2-8°C	Same
Sample Handling/Processing	Automated	Same
Conjugate Antibody	Mouse monoclonal anti-TSH	Same
Unit of Measure	mIU/L	µIU/mL or mIU/L (selectable)
Reference range	Serum - 0.357 – 4.789 mIU/L	Serum - 0.270 – 4.20 µIU/mL
Assay range	Reportable Range : 0.02 to 90 mIU/L	Reportable Range : 0.010 – 100 µIU/mL
Sample Matrix	Human serum	Human serum and plasma
Sample size	200 µL	50 µL
Assay time to first result	17 minutes	18 minutes
Open storage 2-8°C	6 weeks	12 weeks
Open storage on analyzer	6 weeks	Same
Calibration Stability	Calibration is required every 4 weeks	A calibration is required after 1 month when using the same reagent lot, after 7 days when using the same reagent lot on the analyzer.
Calibrators	2 levels – Included in integral	2 levels – Not included with kit
Quality Controls Recommended	3 levels	2 levels

Table 2: Table of Control Similarities and Differences		
Characteristic	**New Device LIAISON® Control Thyroid 1 LIAISON® Control Thyroid 2 LIAISON® Control Thyroid 3**	**Predicate Device Elecsys® PreciControl Universal (K090541)**
Intended Use	Intended for use as assayed quality control samples to monitor the accuracy and precision of the DiaSorin LIAISON® TSH assay	Intended for use as quality control of Elecsys® immunoassays on the Elecsys® and Cobas® e immunoassay analyzers
Matrix	Human serum	Same
Reagent Format	Lyophilized	Same
Storage	Unopened store at 2-8° C until expiration date	Same
Levels	Three concentrations : Low, medium, high	Two concentrations : Low and high
Reagent Format	4 vials x 5.0 mL each level Each level provided separately	2 vials x 3.0 ml each level
Handling	Reconstitue with 5.0 mL distilled water and allow to stand15 minutes before use	Reconstitute with 3.0 mL distilled water and allow to stand 30 minutes before use.
Open Storage	Reconstituted : 48 hours at 2-8° C For longer storage periods, frozen to -20 °C	Reconstituted : On analyzer at 20-25° C up to 5 hrs ; 3 days at 2-8° C; -20° C for up to 1 month

PERFORMANCE DATA for the TSH Assay:

Method Comparison:

One hundred eighty-one (181) samples were tested by the LIAISON® TSH assay and a commercially available immunoassay. The method comparison study was performed according to CLSI EP9-A2 guideline. The samples ranged in concentration from 0.0257 to 89.56 mIU/L.

Results:

Passing & Bablok regression analysis was performed on the results across the range of LIAISON® TSH assay yielding agreement of y = 1.005x-0.0030, R^2 = 0.9748. The 95% confidence interval for slope is 0.988 to 1.026 and 95 % confidence interval for the intercept is -0.0873 to 0.0411 mIU/L.

Reference Range/Expected Values:
Human serum samples from 130 apparently healthy test subjects were tested to determine the reference range for the LIAISON® TSH assay.

Apparently Healthy Test Subjects	Median	Observed 95% Normal Range
Serum (130)	1.438 mIU/L	0.357 – 4.789 mIU/L

Consider these limits as guidelines only. Each laboratory should establish its own reference range

Reproducibility/Precision:
A twenty day precision study was performed at DiaSorin Inc.. A coded panel comprised of 6 frozen serum samples was prepared. The coded panel contained 2 of each level of low, medium and high samples which span the measuring range of the assay. The LIAISON® Control Thyroid (3 levels) were also tested in the study. The CLSI document EP5-A2 was consulted in the preparation of the testing protocol.

The precision panel samples and kit controls were tested on two lots of LIAISON® TSH assay in two replicates per run, 2 runs per day for 20 operating days for a total of 160 replicate results per sample.

The mean, standard deviation, and coefficient of variation (%CV) of the results were computed for each of the tested specimens.

Results:
The 20 day results are summarized in Table 1 as sample overall mean TSH concentration in mIU/L, computed SDs and %CVs for within run and total across lots.

Table 1: DiaSorin Inc.– 20 day Precision Study

Sample ID	N	Mean mIU/L	Between Lot / Within-Site		Total Across Lots / Within Sites	
			SD	%CV	SD	%CV
KC 1	160	0.6401	0.03	4.1%	0.03	4.3%
KC 2	160	8.140	0.19	2.4%	0.39	4.8%
KC 3	160	47.61	0.24	0.5%	2.55	5.4%
Sample 1	160	0.2660	0.01	3.6%	0.01	5.5%
Sample 2	160	1.201	0.03	2.3%	0.05	3.8%
Sample 3	160	4.702	0.07	1.4%	0.20	4.3%
Sample 4	160	28.47	0.35	1.2%	1.01	3.6%
Sample 5	160	46.19	0.25	0.5%	1.80	3.9%
Sample 6	160	82.56	0.21	0.3%	3.47	4.2%

Linearity:
The linearity for LIAISON® TSH assay was determined, based on guidance from CLSI protocol EP6-A. A high TSH sample was serially diluted with LIAISON® Endocrinology Diluent to generate 7 concentrations across the range 0.0150 to 91.3 mIU/L.

Results:
Passing & Bablok regression analysis was performed on the results yielding agreement of y = 0.9807x+0.0013, R^2 = 0.9997. The linearity was measured on the LIAISON® XL Analyzer and has been demonstrated to be linear from 0.02 mIU/L to 90 mIU/L.

LoB/LoD/LoQ:
The Limit of Blank, Limit of Detection and Limit of Quantitation were determined according to CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline June 2012- Second Edition.

LoQ is defined as inter-assay precision of < 20% CV. It was calculated by testing six serum specimens at low TSH doses and assayed in 72 determinations on two different kit lots and two different instruments over three days of testing. The mean, standard deviation, and %CV was then determined for each sample.

Results:
Limit of Blank: 0.014 mIU/L
Limit of Detection: 0.02 mIU/L
Limit of Quantitation: 0.02 mIU/L

Interfering Substances:
Controlled studies of potentially interfering substances and cross reactants showed no interference at the concentration for each substance listed below in the LIAISON® TSH assay. The testing was based on CLSI-EP7-A2. Non-significant interference and cross-reactivity is defined as ≤10% difference between tested and control samples.

Potential Interfering Substances

Substance	**Tested Concentration**
Triglycerides	500 mg/dL
Hemoglobin	250 mg/dL
Unconjugated bilirubin	5 mg/dL
Conjugated bilirubin	5 mg/dL
Albumin	6000 mg/dL

Potential Interfering Cross reactants

Substance	Tested Concentration
Luteinizing Hormone (LH)	1000 mIU/mL
Follicle-stimulating hormone (FSH)	5000 mIU/mL
Human Growth Hormone (hGH)	100 ng/mL
Human Chorionic Gonadotropin (hCG)	200000 mIU/mL
HAMA	1268 ng/mL

Traceability:
The DiaSorin LIAISON® TSH assay is traceable to the WHO reference material: 2nd IRP WHO 80/558 standard.

LIAISON® Control Thyroid 1, LIAISON® Control Thyroid 2, and LIAISON® Control Thyroid 3:

1. Device Description: The LIAISON® Control Thyroid 1, 2 and 3 are prepared from human serum at target values of 0.5-0.78 mIU/L, 7.0-9.48 mIU/L and 42.7-57.7 mIU/L.

2. Stability: The stability of the kit and controls are based on real-time stability study data of one kit lot. Once opened, the kit is stable for 6 weeks at 2-8°C. The sponsor claimed that the kit and calibrators are stable for 6 weeks on-board the LIAISON® XL analyzer and the sponsor requires that it is calibrated every 4 weeks.
   Control Stability: Lyophilized controls are stable until the expiration date shown on the product labeling when stored as instructed.
   Reconstituted controls are stable for up to 48 hours when stored at 2-8°C. For longer storage periods, control aliquots should be frozen to -20°C.

3. Value assignment: A minimum of 60 valid test results for each control are used in the range assignment. The LIAISON® Control Thyroid 1, LIAISON® Control Thyroid 2, LIAISON® Control Thyroid 3 are tested on a minimum of 3 LIAISON® XL Analyzers, using / different approved LIAISON® TSH assay kit lots, at a minimal time period of 3 days. The mean value and the standard deviation (std) is calculated from the test results.
   The target value of the controls is given by the calculated mean value +/- 3 std.

CONCLUSION:

The material submitted in this premarket notification is complete and supports the basis for substantial equivalence to the Roche Elecsys® TSH (K961491) The labeling is sufficient and satisfies the requirements of 21 CFR Part 809.10.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 5, 2013

DiaSorin, Inc
C/O Kelly R. Sauer
1951 Northwestern Avenue
P. O. Box 285
STILLWATER MN 55082-0285

Re: K130469
Trade/Device Name: LIAISON® TSH
LIAISON® Control Thyroid 1
LIAISON® Control Thyroid 2
LIAISON® Control Thyroid 3
Regulation Number: 21 CFR 862.1690
Regulation Name: Thyroid stimulating hormone test system
Regulatory Class: II
Product Code: JLW, JJX
Dated: February 22, 2013
Received: March 1, 2013

Dear Kelly Sauer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k130469

Device Name: LIAISON® TSH
LIAISON® Control Thyroid 1
LIAISON® Control Thyroid 2
LIAISON® Control Thyroid 3

Indications for Use: The DiaSorin LIAISON® TSH assay is an *in vitro* chemiluminescent immunoassay intended for the quantitative determination of thyroid stimulating hormone (TSH), also known as thyrotropin and thyrotropic hormone, in human serum. The test has to be performed on the LIAISON® XL Analyzer. Measurements of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.

The DiaSorin LIAISON® Control Thyroid 1, LIAISON® Control Thyroid 2 and LIAISON® Control Thyroid 3 are intended for use as assayed quality control samples to monitor the accuracy and precision of the DiaSorin LIAISON® TSH assay.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Devices and Radiologic Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Devices and Radiologic Health

510(k) k130469